

Applicant: Patrice Flaherty  
Application No: 10/630,402  
Filing Date: 07/30/2003  
Attorney Docket No: 1066

### **REMARKS**

Claims 1-32 are pending herein.

Claims 12-23 are withdrawn from consideration.

Claims 1-11 and 24-32 are rejected.

Claims 1, 7, 24 and 30-32 are currently amended.

### **Claim Objections**

Claim 8 was objected to because the entered amendments filed 04/09/2007 are ambiguous with respect to the status of claim 8. It was stated that both the remarks and the claim identifier indicated claim 8 is pending whereas line 1 of the claims indicates claim 8 to be canceled. Appropriate correction was required.

It is respectfully submitted that that the previous indication that claim 8 was to be canceled in line 1 of the listing of claims in the amendments filed 04/09/2007 was in error and that claim 8 is therefore still pending. Reconsideration and removal of the objection to the claims is therefore respectfully solicited.

### **Claim rejections under 35 U.S.C. 102**

Claims 1-11 and 24-32 were rejected under 35 U.S.C. 102(b) as being anticipated by Propp (U.S. Pat. No. 5,919,146).

It is respectfully submitted that Propp fails to anticipate claims 1-11 and

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24-32 as set forth herein below.

*Propp fails to disclose invention of claims 1-6 and 32*

It is respectfully submitted that Propp fails to disclose a device comprising "a main tubing segment...an indicator unit and an access port disposed in fluid communication with said main tubing segment in branched relationship to each other...a clamp operably engaging said main tubing segment and adapted to selectively *block and unblock flow of the fluids in both directions* through said main tubing segment...", as set forth in amended claim 1 and defined by claims 2-6 and 32 as dependent therefrom.

In contrast, Propp discloses an anti-reflux valve (74) which is provided in the main tubing segment (40) of the Propp device and is adapted to "prevent reflux of urine towards the bladder" (col. 4, lines 23 and 24 of Propp). The anti-reflux valve (74) facilitates flow of urine toward the sampling device (10) and fluid metering device (48), and therefore, is not adapted to "block and unblock flow of the fluids in both directions through [the] main tubing segment", as set forth in amended claim 1.

Therefore, it is respectfully submitted that Propp fails to anticipate amended claim 1, and claims 2-6 and 32 as dependent therefrom, under 35 U.S.C. 102(b). Reconsideration and allowance of claims 1-6 and 32 is respectfully solicited.

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*Propp fails to disclose invention of claims 7-11*

It is respectfully submitted that Propp fails to disclose a device comprising "a main tubing segment for conveying the blood and the medical fluids; an indicator unit and an access port disposed in fluid communication with said main tubing segment in branched relationship to each other...a clamp operably engaging said main tubing segment and *adapted to selectively block and unblock flow of the fluid in both directions through said main tubing segment*", as set forth in amended claim 7 and defined by claims 8-11 as dependent therefrom.

In contrast, Propp discloses an anti-reflux valve (74) which is provided in the main tubing segment (40) of the Propp device and is adapted to "prevent reflux of urine towards the bladder" (col. 4, lines 23 and 24 of Propp). The anti-reflux valve (74) facilitates flow of urine toward the sampling device (10) and fluid metering device (48), and therefore, is not adapted to "selectively block and unblock flow of the fluids in both directions through [the] main tubing segment", as set forth in amended claim 7.

It is further respectfully submitted that Propp fails to disclose a device comprising "a main tubing segment...an indicator unit and an access port disposed in fluid communication with said main tubing segment in branched relationship to each other...at least one air-permeable and liquid-impermeable membrane provided in said indicator unit and *allowing bidirectional fluid movement between*

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*said indicator unit and said syringe port*", as set forth in amended claim 7 and defined by claims 8-11 as dependent therefrom.

In contrast, the Propp device includes a first vent (60) provided in the metering device (48) and a second vent (28) provided in the urine collection vessel (22). The first vent (60) facilitates flow of urine from the tubing (40) into the metering device (48) when the clamp (54) is open. The second vent (28) facilitates flow of urine from the tubing (40) into the urine collection vessel (22) when the clamp (54) is closed. However, the first vent (60) and the second vent (28) would prevent movement of fluid between the urine collection vessel (22) and the metering device (48) since pressure needed to move the fluid in either direction would be dispelled through these vents.

Therefore, it is respectfully submitted that Propp fails to anticipate amended claim 7, and claims 8-11 as dependent therefrom, under 35 U.S.C. 102(b). Reconsideration and allowance of claims 7-11 is respectfully solicited.

*Propp fails to disclose invention of claims 24-31*

It is respectfully submitted that Propp fails to disclose a device comprising "a main tubing segment...an indicator unit and an access port disposed in fluid communication with said main tubing segment in branched relationship to said main tubing segment and each other...a clamp operably engaging said main tubing

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segment and *adapted to block and unblock flow of the fluids in both directions through said main tubing segment...*", as set forth in amended claim 24 and defined by claims 25-31 as dependent therefrom.

Propp discloses an anti-reflux valve (74) which is provided in the main tubing segment (40) of the Propp device upstream of the bifurcation of the sampling device (10) and the fluid metering device (48). The anti-reflux valve (74) is adapted to "prevent reflux of urine towards the bladder" (col. 4, lines 23 and 24 of Propp) and facilitates flow of urine toward the sampling device (10) and fluid metering device (48); therefore, the anti-reflux valve (74) is not adapted to "block and unblock flow of the fluids in both directions through [the] main tubing segment", as set forth in amended claim 24.

It is further respectfully submitted that Propp fails to disclose a device comprising "a main tubing segment...an indicator unit and an access port disposed in fluid communication with said main tubing segment... at least one air-permeable membrane provided in said indicator unit...wherein said *at least one air-permeable membrane allows bidirectional fluid movement between and through said indicator unit and said access port*", as set forth in amended claim 24 and claims 25-31 as dependent from amended claim 24.

As was set forth herein above, the first vent (60) and the second vent (28) of the Propp device would prevent movement of fluid between the urine collection

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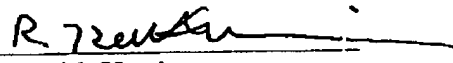
vessel (22) and the metering device (48) since pressure needed to move the fluid in either direction would be dispelled through these vents.

Therefore, it is respectfully submitted that Propp fails to anticipate amended claim 24, and claims 25-31 as dependent therefrom, under 35 U.S.C. 102(b). Reconsideration and allowance of claims 24-31 is therefore respectfully solicited.

*Conclusion*

Every effort has been made to amend applicant's claims in order to define the invention in the scope to which it is entitled. Accordingly, reconsideration and allowance of claims 1-11 and 24-32 is respectfully solicited.

Respectfully submitted,

  
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